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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/823,429

04/12/2004

Peter Miller

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EXAMINER

TATE, CHRISTOPHER ROBIN

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1655

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/823,429	Applicant(s) MILLER ET AL.	
	Examiner Christopher R. Tate	Art Unit 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 April 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 10-12, 22 and 24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 10-12, 22 and 24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11 April 2008 has been entered.

Claims 1 10-12, 22, and 24 are presented for examination on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 10-12, 22, and 24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In claim 1, at lines 7-11, the phrase "wherein said water-soluble extract of cinnamon functions synergistically with said second ingredient at a daily intake of ..." is deemed new matter. That is, no support could be found by the Examiner within the instant specification (including the original claims) concerning a synergistic functional effect with respect to increasing the uptake of creatine (by a muscle of a subject by an insulin dependent pathway)

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between the water-soluble cinnamon extract and the second ingredient (i.e., one or both of the recited creatine compounds) - including at the instantly claimed amount ranges of each.

Although Applicants indicate that support for the claim 1 amendments is found at page 9 and 10 (first paragraph) of the instant specification, no support was found therein for this phrase limitation. The only literal support concerning synergism that the Examiner could find is located at page 3 (first full paragraph) of the instant specification. However, this passage apparently relates to the synergistic effect HMCP (a water-soluble cinnamon extract fraction) has on *in vivo* glucose uptake when used in combination with endogenous insulin.

In claim 24, at lines 2-3, the phrase "element (b) is present in an amount of 94 mg per gram of the dietary supplement" is deemed new matter. That is, no support could be found by the Examiner within the instant specification (including the original claims) concerning the instantly recited amount range (i.e., 94 mg) of element (b). Further, no support for this newly recited amount limitation was pointed to by Applicants within the instant disclosure for this amount limitation.

All other claims depend directly or indirectly from rejected claims and are, therefore, also rejected under USC 112, first paragraph for the reasons set forth above.

Applicant is required to cancel the above new matter recitations, or alternatively to particular point to adequate support therefor within the instant disclosure, in the reply to this Office Action.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 10-12, 14, 22, and 24 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Krotzer (US 2001/0008641) in view of Portsman (US 6,051,236).

Krotzer beneficially teaches a nutritional supplement composition for bodybuilding (including in the form of a solution and/or beverage) which comprises, or may comprise (including as the sole active ingredients therein) creatine monohydrate (designated as a component A), cinnamon (designated as a component D), and glucose or maltose (designated as a component C) therein (see entire document including paragraphs [0011] - [0031], [0060], and Tables A, B, & D). Krotzer does not expressly teach the inclusion of a water-soluble cinnamon extract therein. However, it should be noted that the incorporation of cinnamon within such a solution/beverage would intrinsically read upon a water-soluble cinnamon extract therein since cinnamon is well known in the herbal art to be ground bark from the *Cinnamomum* plant and that the ground bark is naturally water-soluble [thus, ground cinnamon within such a solution/beverage would result in the cinnamon therein reading upon a water-soluble cinnamon extract, as well as one that would intrinsically comprise a fraction (such as HMCP) which is soluble in 0.1N acetic acid, as instantly claimed].

Portman beneficially teaches a nutritional supplement composition (including in the form of a solution and/or beverage) for optimizing muscle performance during exercise which comprises (or may comprise) a water-soluble extract such as a water-soluble cinnamon extract as a flavoring agent so as to advantageously impart a particular taste and sometimes an aroma to the nutritional composition, whereby the flavoring agent is at a level of 0.1 to 2.0 %w/w within the nutritional composition (please note that this level of water-soluble cinnamon extract therein would intrinsically function as instantly claimed, and would also intrinsically comprise a fraction which is soluble in 0.1 N acetic acid as instantly claimed).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to provide a nutritional supplement composition (including in the form of a solution and/or beverage) comprising creatine monohydrate (as component A - as taught by Krotzer), a carbohydrate such as glucose and/or maltose (as component C - as taught by Krotzer), and a water soluble extract of cinnamon (such as the cinnamon taught by Krotzer - which, as discussed above, would intrinsically read upon a water-soluble extract when added to an aqueous solution/beverage; or the water-soluble extract taught by Portsman - as a flavoring agent, which would intrinsically function as claimed), based upon the beneficial teachings provided by the cited references with respect to incorporating such ingredients within a nutritional and/or dietary supplement composition for such purpose. With respect other ingredients that may be taught by the cited references (e.g., the other ingredients taught by Portsman et al), please note that the omission of an element and its function is obvious if the function of the element is not desired (see, e.g., *Ex parte Wu*, 10 USPQ 2031, 1989 - MPEP 2144.04), especially given that Krotzer expressly teaches that one component from each of

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Groups A, C, and/or D may be included as the sole active ingredient(s) therein. The adjustment of particular conventional working conditions (e.g., determining appropriate amount levels thereof) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

Applicants' arguments concerning the USC 103 rejection above have been carefully considered but are not deemed to be persuasive of error in the rejection. Applicants argue that although Krotzer is cited for teaching a nutritional supplement inclusive of creatine monohydrate, cinnamon, and glucose or maltose, and that a logical argument is provided that cinnamon in a beverage would inherently leach water-soluble cinnamon extract, this reference, including in combination with the teachings of Portman et al. (which is cited for teaching a water-soluble cinnamon extract as a flavoring agent), does not teach the essentially closed nature of the pending claims to include essentially only water-soluble cinnamon extract, creatine monohydrate and/or creatine magnesium chelate, and optionally at least one carbohydrate - which is critical in the interpretation of the prior art. Thus, Applicants submit that since the pending claims are limited essentially to these three elements, the pending claim limitations are entitled to patentable weight. However, as noted above, Krotzer beneficially teaches a nutritional supplement composition for bodybuilding (including in the form of a solution and/or beverage) which comprises, or may comprise (including as the sole active ingredients therein) creatine monohydrate (designated as a component A), cinnamon (designated as a component D),

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and glucose or maltose (designated as a component C). Accordingly (as discussed above), with respect to other ingredients that may be taught by the cited references including Krotzer, please note that the omission of an element and its function is obvious if the function of the element is not desired (see, e.g., *Ex parte Wu*, 10 USPQ 2031, 1989 - MPEP 2144.04), especially given that Krotzer expressly teaches that one component from each of Groups A, C, and/or D may be included as the sole active ingredient(s) therein.

Applicants further argue that Krotzer while using cinnamon itself and not a water-soluble extract is admitted to form a water-soluble extract as part of a beverage composition, it nonetheless retains large quantities of nonwater-soluble cinnamon debris that is specifically excluded from the claim language. However, please note that there is no express definition of "a water soluble extract of cinnamon" within the instant specification. Accordingly, as discussed above, the incorporation of cinnamon within such a solution/beverage as taught by Krotzer would intrinsically read upon a water-soluble cinnamon extract therein since cinnamon is well known in the herbal art to be ground bark from the *Cinnamomum* plant and that the ground bark is naturally water-soluble [thus, ground cinnamon within such a solution/beverage would result in the cinnamon therein reading upon a water-soluble cinnamon extract, as well as one that would intrinsically comprise a fraction (such as HMCP) which is soluble in 0.1N acetic acid, as instantly claimed]. Further, please note that the claims, as drafted, do not preclude such a water-soluble cinnamon extract from containing nonwater-soluble cinnamon debris. Applicants further argue that it would not have been obvious to simply modify Krotzer with respect to adding the cinnamon flavoring agent thereto (including in terms of concentration) as taught by Portsman. However, again please note that Krotzer expressly teaches a nutritional supplement composition

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for bodybuilding which comprises, or may comprise one or more components from A-D therein (including as the sole active ingredients therein). Accordingly, the addition of the water-soluble cinnamon extract taught by Portsman (e.g., instead of component D) simply for its well known use as a flavoring agent (including to a bodybuilding nutritional solution/beverage supplement - as beneficially taught by Portsman) to one or more of the bodybuilding compositions disclosed by Krotzer (e.g., one which does not comprise component D) would have been obvious to the ordinary artisan at the time the claimed invention was made, for the reasons fully set forth above. [If Applicants wish to define the water-soluble cinnamon extract within the claimed dietary supplement as a particular water-soluble cinnamon extract fraction (such as HMCP) so as to help distinguish it from those of the cited prior art, it is suggested they do so - within the independent claim.]

Conclusion

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher R. Tate whose telephone number is (571) 272-0970. The examiner can normally be reached on Mon-Thur, 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Christopher R. Tate/
Primary Examiner, Art Unit 1655